CIVIL FALSE CLAIMS ACT COMPLAINT FILED UNDER SEAL PURSUANT TO 31 U.S.C. §§ 3729, *et seq*.

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA *ex rel.* DAVID W. STEBBINS, Plaintiff/Relator, v. MARAPOSA SURGICAL, INC. d/b/a ALLEGHENY VEIN AND VASCULAR; and ROBERT W. TAHARA, M.D., Defendants	Case No. 1:22-cv-10

COMPLAINT

Plaintiff-Relator, David W. Stebbins, by and through his undersigned counsel, brings this *qui tam* action in the name of the United States of America against Defendants, Maraposa Surgical, Inc. d/b/a Allegheny Vein and Vascular and Robert W. Tahara, M.D.

SUMMARY OF CLAIMS

1. Plaintiff-Relator, David W. Stebbins ("Relator"), brings this *qui tam* action on behalf of the United States of America pursuant to the Federal False Claims Act, 31 U.S.C. §§ 3729-3733 (the "FCA"), to recover damages and civil penalties based on the false claims for payment Defendants made and presented, and caused to be made and presented, to the United States.

2. The claims set forth below arise from Defendants' submission of false claims for reimbursement from the Medicare and Medicaid programs for arteriograms allegedly performed

by Defendants. As Defendants knew, their claims were false and fraudulent because, for the reasons set forth below, the arteriograms they performed were not eligible for reimbursement.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because this action arises under the laws of the United States.

4. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) because certain of the Defendants are found in, reside in or transact business in this District and because acts proscribed by 31 U.S.C. § 3729 occurred in this District.

PARTIES

5. Plaintiff is the United States, on behalf of its agencies, the United States Department of Health and Human Services ("HHS") and the Centers for Medicare and Medicaid Services ("CMS").

6. Plaintiff-Relator, David W. Stebbins, is an adult individual residing in this District at 1245 Goodman Street, Pittsburgh, Pennsylvania 15218.

7. Defendant Maraposa Surgical, Inc. ("Maraposa") is a Pennsylvania corporation that was formed in 2004. The registered office of Maraposa is located in this District at 409 Hedgehog Lane, Bradford, Pennsylvania 16701. Maraposa does business as Allegheny Vein and Vascular in this District at 900 Chestnut Street Extension, Suite A, Bradford, Pennsylvania 16701. Allegheny Vein and Vascular is a fictitious name that Maraposa registered with the Commonwealth of Pennsylvania in June 2009.

8. Defendant Robert W. Tahara, M.D. ("Tahara") is a licensed medical doctor who during the period of time relevant to Plaintiff-Relator's claims has done business for Maraposa

under the fictitious name of Allegheny Vein and Vascular. Tahara, at all relevant times, was the President and owner of Maraposa.

9. Defendants' violations of the FCA arose through their submission of claims to, and receipt of funds from, the federal and state funded health care programs based on claims that Defendants knew, or reasonably should have known, were false claims.

FACTS COMMON TO ALL COUNTS

Statutory and Regulatory Background

10. The Medicare Program was established in 1965 through Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq*., to provide a health insurance program for the aged and disabled. Medicare is administered by HHS through CMS and is funded by taxpayer revenues.

11. Section 1833(i)(1)(A) of the Social Security Act requires HHS to specify the surgical procedures that can be performed safely on an ambulatory basis in an ambulatory surgical center ("ASC"). 42 U.S.C. § 1395l(i)(1)(A); *see* 42 C.F.R. § 416(a)(2). An ASC is defined as "any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission." 42 C.F.R. § 416.2.

12. Part 416 of Title 42 of the Code of Federal Regulations sets forth regulations issued by HHS that set forth the conditions that ASCs must meet in order to participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for facility services. *See* 42 C.F.R. § 416.1. In order to participate in the Medicare program as an ASC, an entity must be a party to an agreement with CMS for participation as an ASC and the entity also must comply with the conditions set forth in subparts B and C of Part 416. *Id*. In addition, ASCs "must comply with State licensure requirements." 42 C.F.R. § 416.40.

13. HHS's regulations with respect to the scope of coverage for services provided by ASCs include the following:

> (a) Covered surgical procedures. (1) Effective for services furnished on or after January 1, 2008 through December 31, 2020, covered surgical procedures are those procedures that meet the general standards described in paragraph (b)(1) of this section (whether commonly furnished in an ASC or a physician's office) and are not excluded under paragraph (c) of this section….
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> (b) Requirements for covered surgical procedures –
>
> (1) General standards. Effective for services furnished on or after January 1, 2008 through December 31, 2020, subject to the exclusions in paragraph (c) of this section, covered surgical procedures are surgical procedures specified by the Secretary and published in the Federal Register and/or via the Internet on the CMS Web site that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure….
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> (c) General exclusions effective January 1, 2008 through December 31, 2020. Notwithstanding paragraph (b)(1) of this section, covered surgical procedures do not include those surgical procedures that –
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> (1) Generally result in extensive blood loss;
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> (2) Require major or prolonged invasion of body cavities;
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> (3) Directly involve major blood vessels;
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> (4) Are generally emergent or life-threatening in nature;
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> (5) Commonly require systemic thrombolytic therapy;
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> (6) Are designated as requiring inpatient care under § 419.22(n) of this subchapter;
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> (7) Can only be reported using a CPT unlisted surgical procedure code; or
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> (8) Are otherwise excluded under § 411.15 of this subchapter.

42 C.F.R. § 416.166(b), (c) (emphasis supplied).

14. All of the arteriograms performed by Defendants directly involved major blood vessels.

15. The Medicaid Program was established through Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v, to provide a health insurance program for low-income individuals and families that meet eligibility requirements determined by federal and state law. Medicaid is administered by HHS and the various states and is funded by both state and federal funds. Medicaid pays for items and services pursuant to plans developed by the states and approved by HHS. States pay health care providers according to established rates, and the federal government reimburses the states a statutorily established share of "the total amount expended … as medical assistance under the States' plan." 42 U.S.C. §§ 1396b(a)(1).

16. The Commonwealth of Pennsylvania administers Medicaid through the Office of Medical Assistance Programs of the Commonwealth's Department of Human Services ("DHS"). In order to be reimbursed by Medicaid, a provider of services in the Commonwealth of Pennsylvania must enroll in the Pennsylvania Medicaid Program. *See* 55 Pa. Code § 1101.43. To participate in Pennsylvania's Medicaid program, providers must satisfy various requirements, including complying with applicable standards of practice. In particular:

> In addition to licensing standards, every practitioner providing medical care to MA [Medical Assistance] recipients is required to adhere to the basic standards of practice listed in this subsection. Payment will not be made with the Department's review of a practitioner's medical records reveals instances where these standards have not been met."

55 Pa. Code § 1101.51(d).

17. In administering the Pennsylvania Medicaid program, DHS only pays for "medically necessary compensable services and items" in accordance with DHS Medicaid

regulations. 55 Pa. Code § 1101.61. In addition, DHS pays for compensable services or items rendered if, among other requirements, the services or items are "[w]ithin the practitioner's scope of practice." 55 Pa. Code § 1101.66(a)(1).

18. Chapter 1126 of DHS's regulations sets forth regulations that specifically apply to Medicaid's reimbursement for services provided by ASCs. 55 Pa. Code §§ 1126.1, *et seq*. In its regulations, DHS lists various "noncompensable services and items," including (i) "[a] service not designated by the Department as appropriate to be performed by an ASC," (ii) "[a] service that does not conform to the requirements of this chapter," and (iii) "[a] service provided by an ambulatory surgical center that does not meet the Federal Medicare requirements at 42 C.F.R. 416 (relating to ambulatory surgical services)." 55 Pa. Code § 1126.54(a)(1), (a)(2) and (a)(6).

19. In addition to the DHS's Medicaid-related regulations, the Pennsylvania Department of Health ("DOH") has issued regulations under the Health Care Facilities Act, 35 P.S. §§ 448.101, *et seq*., that govern ambulatory surgical facilities ("ASFs") and the conditions under which ASFs may perform surgeries. The purpose of those regulations "is to protect and promote the public health and welfare through the establishment and enforcement of regulations setting minimum standards in the construction, maintenance and operation of ASFs." 28 Pa. Code § 551.1(c). The standards set forth by the regulations "are intended to assure safe, adequate and efficient facilities and services, and to promote the health, safety and adequate care of the patients of the facilities." *Id*.

20. During the relevant time period, Defendants' facility was not a qualified facility at which arteriograms could be performed. Pennsylvania DOH regulations provide that "[s]urgery shall be performed only in an acute care hospital or in a Class A, Class B or Class C ambulatory surgical facility." 28 Pa. Code § 51.21; *see* 28 Pa. Code § 551.2(a) ("Only those facilities which

are licensed under this subpart shall provide ambulatory surgery in this Commonwealth, except as provided in Class A facilities."); *see also* 28 Pa. Code § 551.3 (broadly defining "surgery" as "[t]he branch of medicine that diagnoses and treats diseases, disorders, malformations and injuries wholly or partially by operative procedures").

21. During the relevant time period, Defendants' facility was not a Class B or C ambulatory surgical facility ("ASF") at which surgeries could be performed, nor was it an acute care hospital. Defendants' facility did not qualify as a Class A ASF at which arteriograms could be performed because under the Pennsylvania DOH regulations, a Class A ASF is "[a] private or group practice office of practitioners where procedures performed are limited to those requiring administration of either local or topical anesthesia, or no anesthesia at all and during which reflexes are not obtunded." 28 Pa. Code § 551.3. Defendants were not permitted to perform arteriograms there because those procedures did not involve the administration of local or topical anesthesia and the reflexes of patients were in fact obtunded through the moderate sedation Defendants administered in connection with the procedures.

22. The arteriograms performed at Defendants' facility and with respect to which Defendants submitted false claims involved the use of moderate sedation. The Pennsylvania DOH regulations prohibit procedures that involve the use of moderate sedation being performed in any facility other than a Class B or C ASF or acute care hospital. *See* 28 Pa. Code § 551.3 (defining classification levels of ASFs). Defendants' facility at which arteriograms were performed, and with respect to which Defendants submitted false claims, was not a Class B or C ASF or an acute care hospital.

23. In addition, the Pennsylvania DOH regulations applicable to ambulatory surgery provide that "[s]urgical procedures may not be of a type that . . . [d]irectly involve major blood

vessels." 28 Pa. Code § 551.21(d)(3). All of the arteriograms performed by Defendants, and for which they submitted false claims, directly involved major blood vessels.

24. The FCA imposes liability for treble damages and civil penalties on anyone who "knowingly presents, or causes to be presented [to the United States] a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1). The definition of "knowingly" includes acting in "deliberate ignorance" or "reckless disregard" of the truth or falsity of the information and does not require proof of specific intent to defraud. 31 U.S.C. § 3929(b)(1).

Defendants' Submission of False Claims

25. The procedures that were the subject of Defendants' false claims were arteriograms. Nearly all arteriograms involve puncturing the femoral artery and inserting a small plastic device approximately three millimeters in diameter. Through this device the physician inserts smaller plastic tubes into the area of interest, which usually is another artery in the leg. The physician then injects contrast (x-ray dye) to demonstrate pathology – which usually is in the form of a blockage in the artery. Once demonstrated, an angioplasty is performed to open the blockage. The procedure is similar to a heart catheterization, but is performed on the legs. In most geographical areas, these procedures are performed in hospitals. However, some physicians, such as defendant Tahara, perform the procedures outside hospitals and in out-patient facilities. Defendants did so without seeking the proper authorization from the Pennsylvania DOH. As is set forth above, the Pennsylvania DOH specifically prohibits procedures from being performed in an ambulatory surgical center when the procedures involve major arteries.

26. The false claims that are the subject of this Complaint are the claims for reimbursement that Defendants submitted with respect to arteriograms performed during the

period of time beginning six years prior to the filing of this Complaint and continuing through the trial of this action.

27. Defendants presented false and fraudulent claims for reimbursement to the United States, through claims submitted to both the Medicare and Medicaid programs, in connection with arteriograms performed at Defendants' facility.

28. On information and belief, Defendants have received substantial payments from the United States in response to their false and fraudulent claims.

29. Defendants' conduct was material. Defendants' conduct had a natural tendency to influence or was capable of influencing the Federal Government to pay Defendants' claims. In particular, to the extent that HHS, CMS and DHS had been aware of Defendants' failure to comply with applicable regulations, such failures would have influenced the decisions to pay for those claims because Defendants' claims were not reimbursable as a matter of law.

30. Defendants submitted claims for Medicare payments for services that were not rendered in compliance with the requirements of applicable regulations pertaining to ASCs' services. The ways in which Defendants' claims for payment by the Medicare program failed to comply with applicable requirements included:

a. Defendants submitted claims for arteriograms that were excluded from "covered surgical procedures" under HHS regulations because they directly involved major blood vessels, in violation of 42 C.F.R. § 416.166(b) and (c);

b. Defendants submitted claims for arteriograms, which were surgical procedures performed in violation of Pennsylvania DOH regulations providing that surgeries may be performed only in acute care hospitals, in Class B or Class C ASFs or in Class A ASFs to a limited extent, 28 Pa. Code § 551.3;

c. Defendants submitted claims for arteriograms that were performed in violation of Pennsylvania DOH regulations that provide that surgical procedures provided by ASFs may not be of a type that directly involve major blood vessels, 28 Pa. Code § 551.21(d)(3); and

d. Defendants submitted claims for arteriograms that were performed in violation of Pennsylvania DOH regulations that prohibit procedures involving the use of moderate sedation being performed in any facility other than a Class B or C ASF or an acute care hospital, 28 Pa. Code § 551.3.

31. Defendants submitted claims for Medicaid payments for services that were not rendered in compliance with the requirements of applicable regulations pertaining to ASCs' services. The ways in which Defendants' claims for payment by the Medicaid program failed to comply with applicable requirements included:

a. Defendants submitted claims for arteriograms in violation of applicable regulations by failing to adhere to the basic standards of practice applicable to participants in Pennsylvania's Medicaid program, 55 Pa. Code § 1101.51(d);

b. Defendants submitted claims for arteriograms that were not within the practitioner's scope of practice, 55 Pa. Code § 1101.66(a)(1);

c. Defendants submitted claims for arteriograms that were "noncompensable services and items" within DHS's regulations because they constituted services not designated by the Department as appropriate to be performed by an ASC, 55 Pa. Code § 1126.54(a)(1);

d. Defendants submitted claims for arteriograms that were "noncompensable services and items" within DHS's regulations because they constituted services that did not conform to the requirements of the regulations, 55 Pa. Code § 1126.54(a)(2);

e. Defendants submitted claims for arteriograms that were "noncompensable services and items" within DHS's regulations because they were services provided by an ASC that did not meet the federal Medicare requirements at 42 C.F.R §§ 416.1, *et seq*. relating to ambulatory surgical services, 55 Pa. Code § 1126.54(a)(6);

f. Defendants submitted claims for arteriograms that were excluded from "covered surgical procedures" because they directly involved major blood vessels, 42 C.F.R. § 416.166(c), 55 Pa. Code § 1126.54(a)(6) and 28 Pa. Code § 551.21(d)(3);

g. Defendants submitted claims for arteriograms, which were surgical procedures performed in violation of Pennsylvania DOH regulations providing that surgeries may be performed only in acute care hospitals, in Class B or Class C ASFs or in Class A ASFs to a limited extent, 28 Pa. Code §§ 51.21, 551.2(a), 551.3; and

h. Defendants submitted claims for arteriograms that were performed in violation of Pennsylvania DOH regulations that prohibit procedures that involve the use of moderate sedation being performed in any facility other than a Class B or C ASF or acute care hospital, 28 Pa. Code § 551.3.

i. Defendants submitted claims for arteriograms that were performed in violation of Pennsylvania DOH regulations that provide that surgical procedures

provided by ASFs may not be of a type that directly involve major blood vessels" (*see* Paragraph 22 above and 28 Pa. Code § 551.21(d)(3)); and

j. Defendants submitted claims for arteriograms that were performed in violation of Pennsylvania DOH regulations that prohibit procedures that involve the use of moderate sedation being performed in any facility other than a Class B or C ASF or acute care hospital (*see* Paragraph 23 above and 28 Pa. Code §§ 51.21, 551.3).

32. Defendants knew, or should have known, that the United States would not pay for such services under the Medicare and Medicaid programs if it had been aware of the fact that the procedures for which the claims were submitted were in violation of law.

33. Through the submission of their false claims, Defendants impliedly certified that the arteriograms that were the subject of the claims were eligible for reimbursement. Defendants' implied certifications were false and fraudulent.

34. Defendants' claims also were false and fraudulent because they omitted material information about their multiple failures to comply with applicable federal and state regulations. Had such information been disclosed to HHS, CMS and DHS by Defendants, Defendants' claims would not have been paid.

35. Defendants' presentment of false and fraudulent claims for payment or approval constituted violations of the FCA, 31 U.S.C. § 3729(a)(1)(A).

36. Defendants' knowing use of false records or statements material to their false and fraudulent claims constituted violations of the FCA, 31 U.S.C. § 3729(a)(1)(B).

37. The United States of America has sustained damages, in an amount to be determined, as a direct and proximate result of Defendants' violations of the FCA.

COUNT ONE
Violations of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A)
Knowingly Presenting False or Fraudulent Claims – Against All Defendants

38. Plaintiff-Relator incorporates Paragraphs 1 through 37 hereof as if set forth in their entirety.

39. Through their wrongful conduct described above, Defendants knowingly presented, or caused to be presented, to officers, employees, or agents of the United States Government false or fraudulent claims for payment or approval.

40. Defendants knew that their claims for payment were false or fraudulent, they were deliberately ignorant that their claims for payment were false or fraudulent, or they acted in reckless disregard of the fact that their claims were false or fraudulent.

41. Plaintiff, the United States, was unaware of the false and fraudulent nature of the claims and Defendants' conduct, and in reliance on the truth and accuracy of the claims made payments to Defendants, which resulted in the United States being damaged in an amount to be established at trial.

COUNT TWO
Violations of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B) –
Knowingly Making, Using or Causing to be Made or
Used, a False Record or Statement – Against All Defendants

42. Plaintiff-Relator incorporates Paragraphs 1 through 41 hereof as if set forth in their entirety.

43. Through their wrongful conduct described above, Defendants knowingly made, used or caused to be made or used, false records and statements material to their false and fraudulent claims allowed.

44. Plaintiff, the United States, was unaware of the false and fraudulent nature of the claims and Defendants' conduct, and in reliance on the truth and accuracy of the claims made payments to Defendants, which resulted in the United States being damaged in an amount to be established at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff-Relator, on behalf of the United States of America, demands judgment against Defendants as follows:

(1) Treble the amount of damages sustained by the United States, in an amount to be established at trial equal to the amount of false claims submitted by Defendants;

(2) Assessment of civil penalties in the amount of $10,000 for each false or fraudulent claim that Defendants made or caused to be made to the United States Government; and

(3) All other necessary and proper relief, including the costs of this action.

Plaintiff-Relator further demands on his behalf:

(1) In the event that the United States of America proceeds with this action or otherwise settles these claims, the Court award to Plaintiff-Relator an amount of the proceeds of this action or settlement of these claims of not less than fifteen percent and as much as twenty-five percent, pursuant to 31 U.S.C. § 3730(d), together with an amount of reasonable expenses incurred by Plaintiff-Relator, plus reasonable attorneys' fees and all costs and expenses incurred by Plaintiff-Relator in bringing this action;

(2) In the event that the United States of America does not proceed with this action, the Court award to Plaintiff-Relator an amount of the proceeds of this action or settlement of these claims of not less than twenty-five percent and as much as thirty percent, pursuant to 31 U.S.C. § 3730(d), together with an amount of reasonable expenses incurred by Plaintiff-Relator, plus

reasonable attorneys' fees and all costs and expenses incurred by Plaintiff- Relator in bringing this action.

DEMAND FOR JURY TRIAL

Plaintiff-Relator demands a trial by jury.

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